UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,005	08/28/2000	Glenn F. Osborne	25527-0005	7486

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EXAMINER
LU, TOM Y

ART UNIT	PAPER NUMBER
2621	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>05 November 2004</u>.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23 and 25-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21, 23 and 25-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All   b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ .

4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: _____ .

DETAILED ACTION

Response to Amendment

1.   The Request for Continued Examination filed on November 5, 2004 has been entered.

2.   Upon entry of the Request for Continued Examination, the amendment filed on November 5, 2004 is entered.

3.   Claims 22 and 24 have been cancelled.

4.   Claims 31-32 are newly added.

5.   Claims 1, 21, 23, 25 and 28 have been amended.

6.   Claims 1-21, 23 and 25-32 are pending.

Response to Arguments

7.   Applicant's arguments filed on November 5, 2004 have been fully considered but they are not persuasive.

The applicant argues the combination of Caple and Kuga does not teach the added limitations of "wherein hybridization information related to said patient comprises hybridization information collected from array comprising peptide nucleic acid probes comprising about 25 to about 70 bases in length tethered to a microarray surface contacted with a clinical sample related to said patient" and "wherein said artificial intelligence comprises application of a rate algorithm adapted to detect changes between said compared parameters and said profile". Upon further review of specification, and in light applicant's arguments, the examiner respectfully disagrees for the following reasons. First of all, with regard to limitation of "wherein hybridization information related to said patient...a clinical sample related to said patient", Kuga at column hybridization information collected from array comprising peptide nucleic acid probes of an

Alzheimer's patient's brain. Although Kuga does not explicitly teach the probes comprise about 25 to about 70 bases in length tethered to a microarray surface, it is inherent that a sample tissue to be analyzed at the nucleic acid level, the probes must be tethered to a microarray surface contacted with a clinical sample related to said patient, which is an Alzheimer's patient's brain tissue in Kuga. In addition, with regard to the length of the probes tethered to the microarray surface, it is a matter of obvious design choice, and a person of ordinary skilled in the art would have been able to made such modification on any hybridization analysis since applicant in the specification does not indicate having the probes about 25 to about 70 bases in length would solve any particular problem nor would it post any significant advantages. Additionally, the limitation of "wherein said artificial intelligence comprises application of a rate algorithm..." is explained in Kuga, column 6, lines 5-9 and 14-20, the routine nucleotide sequencing method is the claimed "rate algorithm".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8.   Claims 1-21, 25-27 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to Claim 1, the scope of the phrase "about 25 to about 70" is unclear.

Claims 2-20 are rejected as being dependent upon Claim 1.

Claim 21 is rejected for the same reason given in Claim 1.

Claim 25 is rejected for the same reason given in Claim 1.

Claims 26-27 are rejected as being dependent upon Claim 26.

Claim 31 is rejected for the same reason given in Claim 1.

Claim 32 is rejected as being dependent upon Claim 31.

Regarding claim 31, the phrase "and/or" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9.   Claims 1-21, 23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caple et al (WO 99/04043) in view of Kuga et al (U.S. Patent No. 5,936,078).

    a. Referring to Claim 1, Caple discloses CPU (note CPU herein is recognized as a computer network, which includes multiple machines, provides services of web server, database server and application server, page 10, line 7) communicates with one user facility (the user facility is a laboratory, page 9, line 22), configured to perform a group of functions comprising receiving and transmitting test results (page 9, line 36) related to said patient (patient with Alzheimer's disease or other disease, page 9, lines 1-20), supporting data analysis (page 10, line 21), and providing security (any communication within a network contains basic encryption, which is considered to be security) and business functions (page 11,

lines 27-33); CPU is configured to perform a group of functions comprising storing data test result, clinical information associated with test result, personal medical history information related to the patient, treatments suitable for diagnosed conditions related to test result, data related information, and statistical information associated with test result (page 10, lines 10-20); CPU is also configured to recognized a diagnostic master user corresponding to a user facility and a diagnostic user corresponding to an individual patient associated with said diagnostic master user, to facilitate information exchanged between the Web server and the database server, and to perform a group of functions comprising statistical comparison and analysis between test result related to the patient received by the Web server, test parameters, personal medical history information supplied by the database server, diagnosing a physiological condition of the patient suggested by the statistical comparison and analysis, and recommending methods of treatment for said patient based on the physiological condition (the facilities, such laboratories act as the claimed "master diagnostic user", individual patients are the claimed "individual patient"). However, Caple does not explicitly disclose the test result is hybridization information, and wherein said hybridization information related to said patient comprises hybridization information collected from array comprising peptide nucleic acid probes comprising about 25 about 70 bases in length tethered to a microarray surface contacted with a clinical sample related to said patient even though Caple does point out at page 10, line 19, stored data in the database can be DNA data or

sequence listing. Kuga at column 3, lines 47-49, teaches finding the treatment for

Alzheimer's disease by comparing the results of the hybridization information

using an image analyzer, which Kuga provides hybridization information that

Caple lacks, and comparing the information with DNA sequences stored in a

database. Additionally, Kuga at column hybridization information collected from

array comprising peptide nucleic acid probes of an Alzheimer's patient's brain.

Although Kuga does not explicitly teach the probes comprise about 25 to about 70

bases in length tethered to a microarray surface, it is inherent that a sample tissue

to be analyzed at the nucleic acid level, the probes must be tethered to a

microarray surface contacted with a clinical sample related to said patient, which

is an Alzheimer's patient's brain tissue in Kuga. In addition, with regard to the

length of the probes tethered to the microarray surface, it is a matter of obvious

design choice, and a person of ordinary skilled in the art would have been able to

made such modification on any hybridization analysis since applicant in the

specification does not indicate having the probes about 25 to about 70 bases in

length would solve any particular problem nor would it post any significant

advantages. Moreover, at the time the invention was made, a person of ordinary

skill in the art to would have been motivated to input hybridization information as

test data in Caple's system because both Caple and Kuga teaches using DNA

sequences to find treatment for Alzheimer's disease, and Caple at page 20, states

his system welcomes modifications and substitutions.

b. Referring to Claim 2, the combination of Caple and Kuga teaches wherein the group of functions performed by said web server further comprises functions selected from the group consisting of product information, product ordering, company information, statistical summary of patient database, request to the application server and security (Caple: page 14, lines 1-21, page 15, lines 25-26).

c. Referring to Claim 3, Caple teaches wherein the data stored by the database server further comprises data selected from the group consisting of genetic pattern database data for chip ID, patient genetic pattern database, and statistical data summary data (Caple: page 13, line 32, page 10, lines 7-9 and 19-20).

d. Referring to Claim 4, the combination of Caple and Kuga teaches wherein the application server constructs at least one query for the database server, and performs at least one statistical comparison between hybridization parameter received by the web server and hybridization parameter supplied by the database server (Caple: page 11, lines 27-32).

e. Referring to Claim 5, the combination of Caple and Kuga teaches wherein the application server is further configured to perform functions selected from the group of functions consisting of data query for chip ID genetic pattern, database query for statistical data summary, pattern match statistical processing, and results output (Caple: page 13, line 32, page 10, lines 7-9 and 19-20).

f. Referring to Claim 6, the combination of Caple and Kuga teaches an operation server (Caple: page 11, line 21).

g. Referring to Claim 7, the combination of Caple and Kuga teaches wherein the operations server comprises functions selected from the group consisting of order management, billing management, and order tracking (Caple: page 11, line 21).

h. Referring to Claim 8, the combination of Caple and Kuga teaches wherein the user facility is linked to said artificial intelligence system through encrypted network connection (see explanation in Claim 1 for encryption, and the laboratory is linked with CPU through cable or phone line).

i. Referring to Claim 9, the combination of Caple and Kuga teaches wherein the user facility is a remote user facility.

j. Referring to Claim 10, the combination of Caple and Kuga teaches wherein the user facility is a local user facility.

k. Referring to Claim 11, the combination of Caple and Kuga teaches wherein the user facility is selected from the group consisting of a hospital, a clinic, a research facility, a business, and a non-profit organization (Caple teaches it can be laboratory).

l. Referring to Claim 12, the combination of Caple and Kuga teaches wherein an optical scanning system to collect hybridization signals from a nucleic acid array, an image processing system to convert optical data from the optical scanning system into a set of hybridization parameters, a computer linked to a network; and a user interface to display data related information (Kuga discloses using an image analyzer to analyze the results of the hybridization, column 3, lines 47-49, such is also described in Caple's, page 9, lines 26, which is linked to CPU).

m. Referring to Claim 13, the combination of Caple and Kuga teaches the network is

the Internet (Caple: page 10, line 4).

n. Referring to Claim 14, the combination of Caple and Kuga teaches the group of

functions consisting of manipulating data, search data, analyzing data, and

displaying data (Caple: page 15, lines 3-6).

o. Referring to Claim 15, the combination of Caple and Kuga teaches wherein the

user interface further comprises displayed information selected from the group

consisting of user information (page 13, line 16, PIN), clinical sample information

(page 13, line 10, sample collection), testing information (page 13, line 20, test

result), clinical information (page 13, line 22, patient history), results report for

biopharma chip, therapeutic choices, and billing information (page 13, lines 35-

37).

p. Referring to Claim 16, the combination of Caple and Kuga teaches wherein the

data related information is selected from the group consisting of hybridization

information (Kuga: column 3, line 45), patient information, statistical

information, clinical information, medical information, diagnosis information,

treatment information, biological information, product information, and company

information (Caple: page 13, lines 7-37).

q. Referring to Claim 17, the combination of Caple and Kuga teaches wherein the

user facility further comprises functions selected from the group consisting

genetic pattern processing (Caple: sequence listings, page 10, line 19), request for

pattern match for chip ID and report generation (Caple: unique bar-coded ID, page 13, line 21).

r. Referring to Claim 18, the combination of Caple and Kuga teaches a computer linked to a network (Caple: page 10, line 3, CPU); and a user interface to display data related information (Caple: page 10, line 5, display).

s. Referring to Claim 19, the limitations are addressed in Claim 16.

t. Referring to Claim 20, the combination of Caple and Kuga teaches a system architecture based on a shared processing functionality between at least one remote location and at least one central data processing facility (Caple: figure 1).

u. With regard to Claim 21, the only difference between Claim 1 and Claim 21 is Claim 21 calls for additional limitations of "a patient identifier related to said patient", Caple at page 13, line 16, teaches personal identification numbers for patients; and "updating said stored hybridization parameters and said stored patient medical history", Caple teaches monitoring and tracking patients' health and provide health services based on patients' treatment history, page 15, lines 25-28, also it would be reasonable to assume a person of ordinary skill in the art would like to update the test result data such as hybridization parameters as taught in Kuga since the test data would be part of medical history.

v. With regard to Claim 23, the only difference between Claim 21 and Claim 23 is Claim 23 calls for collecting information from a "proteomics chip", which Kuga at column 3, line 45, teaches cDNA probes, and the limitation of "wherein said artificial intelligence comprises application of a rate algorithm adapted to detect

changes between said compared parameters and said profile" is explained in Kuga, column 6, lines 5-9 and 14-20, the routine nucleotide sequencing method is the claimed "rate algorithm".

w. With regard to Claim 25, the only difference between Claim 21 and Claim 25 is Claim 25 calls for "living organism", which a patient is a living organism.

x. With regard to Claim 26, the combination of Caple and Kuga does not explicitly teach the living organism is an animal. However, it is well known in the art that all living beings, such as human beings, animals and plants, contains DNA sequences, which the combination of Caple and Kuga teaches analyzing DNA sequences to find treatments for a particular disease, such as Alzheimer's disease. In addition, as Caple at page 20, lines 5-7, teaches it is understood to that various modifications and substitutions can be made to the system, which a person of ordinary skill in the art would have been motivated to modify Caple's system to perform analysis for an animal.

y. With regard to Claim 27, the combination of Caple of Kuga can be modified to perform analysis on a plant, the motivation is provided in Claim 26.

z. With regard to Claim 28, see explanation in Claims 23 and 25.

aa. With regard to Claim 29, see explanation in Claim 26.

bb. With regard to Claim 30, see explanation in Claim 27.

cc. With regard to Claim 31, see explanation in Claim 1.

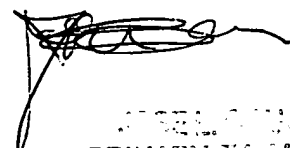dd. With regard to Claim 32, see explanation in Claims 2-5.

Conclusion

10.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tom Y Lu whose telephone number is (703) 306-4057. The examiner can normally be reached on 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo H Boudreau can be reached on (703) 305-4706. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tom Y. Lu